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February 13, 2023

VIA ELECTRONIC SUBMISSION

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-4201-P
P.O. Box 8013
Baltimore, MD 21244

Re: RIN: 0938-AU96: Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications (CMS-4201-P)

Dear Administrator Brooks-LaSure:

The Medicare Rights Center (Medicare Rights) appreciates this opportunity to comment on the **Medicare Program; Contract Year 2024 Policy and Technical Changes** proposed rule. Medicare Rights is a national, nonprofit organization that works to ensure access to affordable and equitable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives. Each year, Medicare Rights provides services and resources to over three million people with Medicare, family caregivers, and professionals.

General Comments

Overall, we were very pleased to read these proposed rules from the Centers for Medicare & Medicaid Services (CMS), and our responses are supportive. Increasing equity within the health care system is vital and we applaud attempts to embed equity further into Medicare, including by improving access to substance use disorder and mental health care. In addition, prior authorization, inappropriate coverage denials, and predatory marketing are of particular concern to us as they interfere with access to care and beneficiary decision-making. We appreciate the proposals to curb these harmful practices and urge

CMS to build on these reforms in future rulemaking and guidance. Similarly, while we are encouraged to see increased deference to provider decisions, especially in post-acute settings, more must be done to ensure care decisions are based on medical and clinical needs, not profit-seeking or business ones.

We are disappointed, however, that the proposals do not address several important issues in detail or depth: appeals; proliferation of plans and meaningful difference; marketing guidance and oversight for supplemental benefits; sales commissions and other problematic incentives; and weakened network adequacy requirements.

Throughout and in general, we urge CMS to provide more robust oversight of both Medicare Advantage (MA) and Part D plans to ensure they are meeting their contractual and civic duties to beneficiaries, taxpayers, and Medicare. We appreciate this may require additional CMS staff and resources, which we urge the agency to pursue as necessary.

Appeals

The MA and Part D appeals systems are overly burdensome and difficult to navigate. A recent Kaiser Family Foundation (KFF) analysis showed only 11% of prior authorization denials were appealed in 2021. Of those, more than 80% were later overturned, either completely or in part.¹ A 2018 Health and Human Services Office of the Inspector General (OIG) investigation raised similar concerns, finding that while only 1% of prior authorization denials were appealed, 75% were overturned at the first level of review.² These reports, and our own experiences with helpline callers, clients, and other professionals, suggest improper denials are far too common and beneficiary appeals far too rare: in 2021 alone, erroneous denials accounted for nearly one-third of all calls to our helpline. Of those, 65% were about how to appeal a plan's decision.³

Coverage denials force beneficiaries to choose between seeking other care, paying out-of-pocket, or going without—or getting embroiled in a daunting appeals system. The low rate of appeals indicates the complexity of the process. We often hear from enrollees who don't know how to begin, as well as from those who can't; they simply don't have time to wait for treatment or to wade through what might be a thicket of denials across all of their care.

Importantly, even successful appeals come at a cost. The most significant risks are care delays and the resulting negative health outcomes. But appeals processes are also burdensome for beneficiary and provider alike, creating strain, expense, and extra work. Many beneficiaries abandon the process altogether, along with the care they need. And when plans systematically and inappropriately deny

¹ Jeannie Fuglesten Biniek & Nolan Sroczyński, "Over 35 Million Prior Authorization Requests Were Submitted to Medicare Advantage Plans in 2021," (February 2, 2023), <https://www.kff.org/medicare/issue-brief/over-35-million-prior-authorization-requests-were-submitted-to-medicare-advantage-plans-in-2021/>.

² U.S. Department of Health and Human Services Office of Inspector General, "Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials," (September 25, 2018), <https://oig.hhs.gov/oei/reports/oei-09-16-00410.asp>.

³ Medicare Rights Center, "Medicare Trends and Recommendations: An Analysis of 2020-2021 Call Data from the Medicare Rights Center's National Helpline," (May 2022), <https://www.medicarerights.org/pdf/2020-2021-helpline-trends-report.pdf>.

claims, it may have a chilling effect on providers' willingness to prescribe or provide a treatment or cause providers to spend additional time and resources "over proving" claims to avoid denials.

Appeals are a necessary safety valve and important quality marker, but currently function as a very poor substitute for sound plan decisions or robust independent oversight. Both the denials that unnecessarily force people into a broken appeals system, and that system itself, must be addressed.

To reduce harmful and inaccurate denials—and the likelihood that an enrollee needs to file an appeal in the first place—we urge clearer rules, stronger enforcement, and more transparency. The newly finalized Risk Adjustment Data Validation (RADV) rule is a step in the right direction.⁴ The OIG has also recommended tightening audit standards on MA plans, establishing firmer guidance about MA coverage criteria, and directing MA plans to review their processes and systems to better avoid payment errors.⁵ We agree with these reforms and ask CMS to notify beneficiaries about plan violations, offering enrollment relief where needed.

MA plans that inappropriately deny care must not be permitted to benefit from it. Capitation provides a motive to deny or delay access to care, but penalties for bad actors can help reduce the force of this incentive. Or, if the decisions are simply mistakes, corrective actions from CMS can spur plans to take more care in their process design and decision-making.

We additionally urge CMS to revise regulations, manual provisions, and other guidance to require plans to disclose to providers and enrollees the Medicare criteria or specific plan policies upon which coverage denials or terminations are made, along with relevant citations.

To enhance data collection and reporting efforts, we ask CMS to monitor MA coverage and care decisions for high denial and overturn rates as well as for low appeal rates, and for patterns therein, like inappropriate denials for specific services or categories of care. Any trends that emerge should trigger a more comprehensive review to determine the underlying cause of the error and to obligate the plan to resolve it. Plans that regularly engage in such practices should lose the ability to enroll new members or, if the violations are severe, to contract with CMS, until corrections are made and publicly documented. Offending plans should remain subject to higher levels of review going forward and all captured data should be made publicly available. Finally, to best obtain the full range of data about pre- and post-service denials, we ask the agency to rescind the September 2020 guidance improperly limiting reported elements.⁶

⁴ 88 FR 6643.

⁵ U.S. Department of Health and Human Services Office of Inspector General, "Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care," (April 2022), <https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf>.

⁶ Centers for Medicare & Medicaid Services, "Revised Appeal and Grievance Data Form, Form CMS-R-0282," (September 24, 2020), <https://www.hhs.gov/guidance/document/revised-appeal-and-grievance-data-form-form-cms-r-0282>. (Removed the following data elements from the standardized Appeal and Grievance Data Form [Form CMS-R-0282] Expedited appeals; Disposition of expedited appeals, IRE (level 2) appeals, Disposition of IRE (level 2) appeals, Withdrawals).

We continue to urge CMS to simplify its appeals systems, without delay. This includes improving plan communications with enrollees. Under current rules, when plans issue a denial, they are required to notify the affected enrollee in a timely manner. This notification should contain everything the enrollee needs to determine next steps, which may involve pursuing an appeal. Without this notice, beneficiaries may not understand their rights, how to appeal, or even that they have been denied coverage. Despite the importance of this obligation, many plans fail to comply.⁷ CMS must do more to make sure plan notices are correct, promptly delivered, available in languages other than English, and accessible to people with varying levels of health literacy. We also support invalidating and immediately escalating coverage denials that were not accompanied by proper notice.

In all cases, the first level of appeal should be handled by an independent entity, rather than the plan itself. This would simplify the system, help ensure beneficiaries have more timely access to care, and better encourage plans to make accurate initial coverage determinations.

Reforms are more urgent than ever as Medicare prepares for the Inflation Reduction Act's (IRA) landmark policy changes. Among its structural improvements, the IRA simplifies the Part D benefit and places a greater liability on plan sponsors in the catastrophic coverage phase. While we support this essential redesign, we are concerned it may incentivize more aggressive utilization management, putting more people at risk of experiencing a coverage denial and a dysfunctional appeals system. In addition, because the bill's critical limitations on cost sharing and total out of pocket obligations are only applicable to covered drugs, improper denials and burdensome, slow appeals could result in poor medication adherence and limitless costs, undermining the impact of this long-overdue legislative victory.

Plan Proliferation

The proposed marketing and advertising proposals tangentially address the issue of plan choice, but there is a more fundamental issue preventing people with Medicare from making optimal decisions about their coverage: the plan landscape is overwhelmingly cluttered. Recent rule changes, such as the elimination of meaningful difference and uniformity requirements, as well as reduced network adequacy standards and booming profits—in part due to MA overpayment—has led to an influx of plans, with single sponsors often offering multiple plans in any given area.⁸ During open enrollment for 2023, the average beneficiary had 43 different MA plans from which to choose. This is more than double the number in 2018 and does not even include employer-sponsored plans, Special Needs Plans (SNPs), cost plans, or Medicare-Medicaid integrated plans, all of which are additionally available to some beneficiaries,⁹ or fully capture geographic differences. In 27 counties, more than 75 plans were offered.

⁷ In 2015, 45% of Medicare Advantage plans sent denial letters with incomplete or incorrect information. See HHS Office of Inspector General, "Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials" (September 2018), <https://oig.hhs.gov/oei/reports/oei-09-16-00410.pdf>.

⁸ Medicare Payment Advisory Commission, "Medicare Payment Policy: Report to the Congress," (March 2022), https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_SEC.pdf.

⁹ Meredith Freed, et al., "Medicare Advantage 2023 Spotlight: First Look" (November 10, 2022), <https://www.kff.org/medicare/issue-brief/medicare-advantage-2023-spotlight-first-look/>.

Most beneficiaries (60%) had plans available from fewer than 10 companies. In 1,136 counties (accounting for 50% of beneficiaries), at least one company offered 10 or more plans. This is also reflected in the enrollment numbers. Two companies, UnitedHealthcare and Humana, accounted for 46% of MA enrollment in 2022.

Plans can vary on everything from costs to coverage, sometimes in subtle but important ways. For most beneficiaries, this makes close analysis both critical and unattainable. Indeed, identifying and simultaneously comparing each plan deviation, year after year, is a challenging, intimidating, and time-consuming task that few people with Medicare perform.¹⁰ Instead, they may rely on heuristics like where their neighbors or friends get coverage. Worse, they may rely on marketing that is designed to lure them with promises of benefits they may not be eligible for or that may be so limited as to be essentially worthless.

Complex analyses of seemingly endless plan designs may be particularly burdensome for consumers with limited English proficiency, those who have cognitive impairments or other serious health needs, and people with inadequate internet access. Despite the severe consequences of making a poor plan choice—such as high costs, restricted provider access, and delayed care—there are few remedies. If an enrollee makes a mistake, they may be stuck in a plan that does not meet their needs for up to a year, or locked into MA indefinitely because of the high cost of Medigap coverage.

Standardization, with only high-quality options, removes some of this complexity and risk. There is precedent for such an approach. Medigap plans are standardized to facilitate comparison, and CMS is beginning to address plan overload in Marketplace coverage, including by offering standardized plans and increased discussion of meaningful differences between plans.¹¹ We urge similar consideration in the MA space to help people with Medicare coverage make better decisions.

In addition to easing plan evaluations, offering standardized plans would advance equity by making it easier for CMS, consumers, advocates, and researchers to identify and prevent discriminatory benefit designs, such as plans that leave individuals with particular conditions or medication needs with substantial out-of-pocket costs.

Marketing Guidance and Oversight for Supplemental Benefits

It is alarming that CMS has not yet established clear rules about how MA plans and brokers may market supplemental benefits to current or potential enrollees. According to a recent Commonwealth Fund

¹⁰ See, e.g., Meredith Freed, et al., “More Than Half of All People on Medicare Do Not Compare Their Coverage Options Annually,” Kaiser Family Foundation (October 29, 2020), <https://www.kff.org/medicare/issue-brief/more-than-half-of-all-people-on-medicare-do-not-compare-their-coverage-options-annually/>; Wyatt Korma, et al., “Seven in Ten Medicare Beneficiaries Did Not Compare Plans Past Open Enrollment Period,” Kaiser Family Foundation (October 13, 2021), <https://www.kff.org/medicare/issue-brief/seven-in-ten-medicare-beneficiaries-did-not-compare-plans-during-past-open-enrollment-period/>.

¹¹ Centers for Medicare & Medicaid Services, “HHS Notice of Benefit and Payment Parameters for 2024 Proposed Rule” (December 12, 2022), <https://www.cms.gov/newsroom/fact-sheets/hhs-notice-benefit-and-payment-parameters-2024-proposed-rule>.

analysis, 24% of those who opted for MA were drawn by the extra benefits.¹² Yet, no marketing guardrails exist. We urge CMS to rectify this, and to reinforce that supplemental benefits should not be merely or primarily a sales tool or used to persuade beneficiaries to enroll in a plan. We also ask the agency to be vigilant in its enforcement of existing rules, including by watching for unusual spikes in enrollment and other patterns that might indicate inappropriate behavior. When identified, such practices must be corrected, including through plan and broker penalties and enrollment remedies such as Special Enrollment Periods.

Sales Commissions and Other Sales Issues

Commonwealth Fund analysis also found that most people who received help choosing between their coverage options turned to brokers and agents.¹³ But these representatives are not always objective; they receive commissions, which may not be equal between products.¹⁴ For example, commissions that are higher for MA plans than for supplemental coverage like Medigap may incentivize agents and brokers to steer consumers into MA. We urge CMS to require brokers and agents to reveal commissions, commission residual schedules, bonuses, and other financial incentives they receive for any given enrollment. We also ask CMS to require that agents and brokers identify themselves as such, and not disguise their financial interest behind terms like “advisor” or “navigator.” Such disclosures are a necessary and long overdue step towards transparency. Further, we urge CMS to consider imposing fiduciary duties on agents and brokers to ensure that they are acting in the beneficiary’s best interest.

We also ask CMS to more actively promote and advocate for increased funding for State Health Insurance Assistance Programs (SHIPs). Despite being a primary, trusted source of unbiased enrollment counseling, their funding is unable to keep pace with growing demands, which are in part being driven by MA enrollment increases and an ever-more complex plan selection process. To better help SHIPs provided needed assistance, we recommend seeking adequate funding in the President’s budget requests to Congress.

Weakened Network Adequacy Requirements

While the proposed rule would strengthen network adequacy in some areas, a step we appreciate and support, it would not undo the 2021 Part C & D rule which diluted network adequacy in non-urban counties, and in all areas with respect to dialysis and certain telehealth services.¹⁵ These policy changes threaten beneficiary access to care, and we continue to urge their immediate reversal.

Network adequacy should be a stringent threshold question. If an MA plan cannot contract with enough providers to meet minimum “time and distance” standards, it should not be allowed to offer a plan in

¹² Faith Leonard, et al., “Traditional Medicare or Medicare Advantage: How Older Americans Choose and Why,” (October 17, 2022), <https://www.commonwealthfund.org/publications/issue-briefs/2022/oct/traditional-medicare-or-advantage-how-older-americans-choose>.

¹³ *Id.*

¹⁴ Riaz Ali & Lesley Hellow, “Agent Commissions in Medicare and the Impact on Beneficiary Choice,” (October 12, 2021), <https://www.commonwealthfund.org/blog/2021/agent-commissions-medicare-and-impact-beneficiary-choice>.

¹⁵ 85 FR 33796, 33854.

the area. Permitting plans to operate with too few providers that are too far away from enrollees does not serve people with Medicare well. Nor does using access to telehealth—services that should supplement and not supplant in-person care—as an excuse to reduce plan compliance.

II. Implementation of Certain Provisions of the Bipartisan Budget Act of 2018, the Consolidated Appropriations Act, 2021, and the Inflation Reduction Act of 2022

A. Applying D-SNP Look-Alike Requirements to Plan Benefit Package Segments

CMS proposes several changes to strengthen its ability to limit D-SNP look-alikes, up to and including plan termination. We support these proposals, though we urge consideration of lowering the threshold to qualify as a look-alike to 50% or higher enrollment of dually eligible individuals.

B. Part D Special Enrollment Period Change Based on CAA Medicare Enrollment Changes

CMS proposes to revise the start and end date for the SEP for Individuals Who Enroll in Part B During the Part B GEP to align with the Part B entitlement dates for someone who enrolls in Part B using the GEP that starts January 1, 2023 and to revise the effective date of the individual's Part D plan enrollment to be effective the first of the month following the month the Part D plan sponsor receives the enrollment request. We support this update.

C. Alignment of Part C and Part D Special Enrollment Periods with Medicare Exceptional Condition Enrollment

CMS proposes to add corresponding exceptional condition SEPs for MA and Part D enrollment to align with the new Medicare premium Part A and B exceptional condition SEPs. The SEPs would begin when the individual submits the application for premium Part A and Part B, or only Part B, and continue for the first 2 months of enrollment in Part A (premium or premium-free) and Part B. The enrollment would be effective the first of the month following the month the MA or Part D plan receives the enrollment request. We support this proposal.

D. Transitional Coverage and Retroactive Medicare Part D Coverage for Certain Low-Income Beneficiaries Through the Limited Income Newly Eligible Transition (LI NET) Program

We support the many proposals to implement LI NET changes and appreciate the work CMS has done to develop and sustain this important program.

E. Expanding Eligibility for Low-Income Subsidies Under Part D of the Medicare Program

CMS proposes to implement the IRA provisions expanding full LIS eligibility to 150% of the federal poverty level. We strongly support these changes, which will effectively sunset the partial subsidy income requirements after 2023, and encourage robust outreach to maximize enrollment.

III. Enhancements to the Medicare Advantage and Medicare Prescription Drug Benefit Programs

A. Health Equity in Medicare Advantage (MA)

2. Ensuring Equitable Access to Medicare Advantage (MA) Services

CMS proposes to include more examples of underserved populations to whom an MA organization must ensure that services are provided in a culturally competent manner, as well as to promote equitable access to services in order to satisfy the existing requirement. We greatly appreciate and support the inclusion of additional populations.

The proposed new list would be as follows: (i) people with limited English proficiency or reading skills; (ii) people of ethnic, cultural, racial, or religious minorities; (iii) people with disabilities; (iv) people who identify as lesbian, gay, bisexual, or other diverse sexual orientations; (v) people who identify as transgender, nonbinary, and other diverse gender identities, or people who were born intersex; (vi) people who live in rural areas and other areas with high levels of deprivation; and (vii) people otherwise adversely affected by persistent poverty or inequality. We urge CMS to clarify the meaning of item (vi) “people who live in... other areas with high levels of deprivation.”

3. Medicare Advantage (MA) Provider Directories

CMS proposes to mirror the Medicaid provider directory requirements by adding the phrase “each provider’s cultural and linguistic capabilities, including languages (including American Sign Language) offered by the provider or a skilled medical interpreter at the provider’s office.” We support this addition.

CMS also proposes to add a new required provider directory data element for providers who to treat patients with medications for opioid use disorder (MOUD). Given the removal of the waiver requirement in the 2023 Consolidated Appropriations Act, we assume the waiver-specific language will also be removed. However, we strongly support adding an identifier to help beneficiaries find MOUD-trained providers.

If finalized, CMS intends to monitor organization compliance with the proposed new requirements through periodic online provider directory reviews. We support additional reviews and significant penalties for errors. Without reliable directories, beneficiaries cannot find and contact network providers that meet their various needs. We urge additional efforts to ensure that providers submit correct information and any relevant changes in their practices, and that plans collect correct information and regularly review provider submissions.

We caution, however, that enrollees should still be encouraged to contact providers directly to confirm information found within.

4. Digital Health Education for Medicare Advantage (MA) Enrollees Using Telehealth

CMS proposes to require MA organizations to develop and maintain procedures to identify and offer digital health education to enrollees with low digital health literacy to assist with accessing any

medically necessary covered benefits that are furnished when the enrollee and the provider are not in the same location using electronic exchange. We support this proposal.

In addition, we urge CMS to carefully define terms to ensure clarity between digital literacy, health literacy, health insurance literacy, and other aspects of beneficiary understanding of their benefits, diagnoses, treatment options, modalities for accessing care, and other issues. We also encourage CMS to continue to work with other federal and state agencies to address additional aspects of the digital divide, including access to technological devices, data plans, and broadband.

CMS proposes that MA organizations would have to introduce a digital health literacy screening program but would have flexibility to design their own screening program or procedure. In addition, CMS proposes that MA organizations would then implement their chosen digital health education program. While we are agnostic on the ability of MA organizations to design appropriate programs, we urge CMS to impose minimum standards, and to monitor these designs, programs, and procedures for efficacy and fairness.

CMS also proposes to require MA organizations to make information about these programs available to CMS upon request but seeks comment on whether the agency should require regular reporting of this data alongside other Part C reporting requirements. We urge CMS to require regular reporting to ensure that MA organizations comply with the requirement.

5. Quality Improvement Program

CMS proposes to require MA organizations to incorporate one or more activities into their overall Quality Improvement (QI) programs that reduce disparities in health and health care among their enrollees. The proposal would require MA organizations to ensure the activities are broadly accessible irrespective of race, ethnicity, national origin, religion, sex, or gender. We support this requirement, though we urge strong oversight to ensure the MA organizations do not just check a series of boxes, but meaningfully engage with enrollees as well as national, state, and local groups to better understand enrollee needs and existing resources. CMS's intention to be non-prescriptive and flexible may allow innovative and important results, but it may also result in lackluster efforts that do nothing to improve enrollee health and well-being.

B. Behavioral Health in Medicare Advantage (MA)

2. Behavioral Health Specialties in Medicare Advantage (MA) Networks

Currently, MA organizations are required to demonstrate that they meet network adequacy for two behavioral health specialty types, (1) psychiatry and (2) inpatient psychiatric facility services. CMS proposes to add three new provider specialty types: (1) clinical psychology, (2) clinical social work, and (3) MOUD prescribers. We strongly support these proposals. In particular, establishing network adequacy standards for prescribers of MOUD will both incentivize MA plans to offer more favorable network contracts to opioid treatment programs (OTPs) and increase access to this evidence-based standard of care for all Medicare beneficiaries.

CMS proposes to add travel time and distance standards for the new provider categories. We support the addition of such standards and recommend they mirror those used for primary care physicians to best increase access to these vital services and to reduce disparities between physical and behavioral health care services. MOUD services often require frequent, sometimes daily, visits.

CMS proposes to amend the list of health care providers in the existing access to services standards to include providers that specialize in behavioral health services. We strongly support this proposal.

CMS also proposes to allow these specialty providers to count towards a plan's network adequacy credits if they provide services via telehealth. We oppose this proposal and reiterate our position that it is inappropriate to allow a credit for telehealth. Enrollees must not be shunted into telehealth with no in-person options, and MA plans must not be permitted to shortchange network adequacy in any way.

3. Behavioral Health Services in Medicare Advantage (MA)

CMS proposes to add behavioral health services to the types of services for which MA organizations must have programs in place to ensure continuity of care and integration of services. CMS also proposes to clarify that an emergency medical condition can be physical or mental in nature. We strongly support these proposals.

4. Medicare Advantage (MA) Access to Services: Appointment Wait Time Standards

CMS proposes to codify appointment wait times as standards for primary care services that are the same as the appointment wait times described in the Medicare Managed Care Manual and to extend those standards to behavioral health services. We support this proposal. We encourage CMS to separate out mental health and substance use disorder services for this metric to ensure they can be tracked individually. This will best promote sufficient and timely access to both. We agree that MA plans should be required to achieve the appointment wait time metrics for each service type for a minimum of 95% of plan enrollees.

C. Medicare Advantage (MA) Network Adequacy: Access to Services

CMS proposes to more clearly state the scope of the MA organization's obligation to ensure adequate access to medically necessary covered benefits by requiring MA organizations offering coordinated care plans to arrange for any medically necessary covered benefit outside of the plan provider network, at in-network cost sharing rates, when an in-network provider or benefit is unavailable or inadequate to meet an enrollee's medical needs. We support this proposal. Plan enrollees should be able to rely on MA network adequacy. If a network is inadequate, the plan should not be permitted to avoid responsibility by foisting the financial burden onto the enrollees.

In addition, we urge CMS to include post-acute rehabilitation programs, such as inpatient rehabilitation hospitals and units (IRFs), comprehensive outpatient rehabilitation facilities (CORFs), and long-term acute care hospitals (LTCHs) in the list of facility specialty types evaluated during network adequacy reviews. These are critical settings of care for people in need of rehabilitation services.

D. Enrollee Notification Requirements for Medicare Advantage (MA) Provider Contract Terminations

CMS proposes applying more stringent enrollee notification requirements when primary care and behavioral health provider contract terminations occur. Given the significant disruptions in care that can result from provider contract terminations, we strongly support the proposed changes. In particular, we welcome those to strengthen requirements regarding “no cause” terminations, the expansion of the population of affected individuals who are patients of behavioral health providers, and the requirement of both written and telephonic notice for these providers where disruption is particularly challenging. We often hear from enrollees who have been caught off guard to discover their provider is no longer in network mid-year, and who are experiencing extreme disruptions to their course of care as a result.

CMS also solicits comment on its proposal to consider an enrollee who is impacted by a provider contract termination to be experiencing an exceptional condition for SEP purposes or, alternatively, the adoption of a new SEP for this type of provider contract termination, with explicit standards for when termination of a provider from the network should serve as a basis for SEP eligibility. We support easing access coverage changes for impacted enrollees through an SEP and do not have a strong preference between the two outlined approaches. But we note that in either case the existence and applicability of the SEP should be included in the required beneficiary notice and other applicable materials.

E. Utilization Management Requirements: Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization, Additional Continuity of Care Requirements, and Annual Review of Utilization Management Tools (§§ 422.101, 422.112, 422.137, and 422.138) (p 130)

2. Coverage Criteria for Basic Benefits

We appreciate these proposals and urge CMS to do more to curtail inappropriate and aggressive use of utilization management that can hinder access to care, both through outright denials and approvals that are too limited in duration or scope.

CMS proposes to clarify that when making coverage decisions, MA organizations must comply with general coverage and benefit conditions as outlined in Original Medicare laws, unless they have been superseded by laws specifically applicable to MA plans. We strongly support this clarification. Inappropriate denials, including due to incorrect interpretations of coverage rules, interfere with enrollees and providers working together to develop and execute diagnosis and treatment regimens. Callers to our national helpline regularly report difficulty accessing Medicare-covered services through their MA plans because of prior authorization and other utilization management restrictions. These practices leave enrollees with a handful of inferior options: paying out of pocket, trying other services (which are definitionally second-choice), going without care entirely, or delving into the labyrinthine MA appeals process. Clarifying that rules governing scope of coverage for Original Medicare also apply to MA—as well as enforcing these rules—could help more enrollees avoid these difficult decisions.

CMS also proposes to codify that MA organizations may not deny coverage of an item or service based on internal, proprietary, or external clinical criteria not found in Original Medicare coverage policies, and that utilization management processes, such as clinical treatment guidelines that require another item

or service be furnished prior to receiving the requested item or service, would violate the proposed requirements and therefore be prohibited unless it is specified within the applicable NCD, LCD, or Medicare statute or regulation. We strongly support this proposal.

CMS notes that it is not removing the authorization for MA plans to use step therapy policies for Part B drugs under certain circumstances. We continue to be concerned about the negative impact this allowance may have on access to care. Like prior authorization, step therapy is a form of utilization management that can prevent or delay needed therapies.

Continued use of step therapy for Part B medications is problematic, in part, because treatment decisions should be made at the clinical, not plan, level and be based on clinical literature and treatment guidelines as well as individual circumstances. MA plans should be given explicit injunctions against creating barriers to provider-directed care.

CMS reaffirms that it did not authorize step therapy practices for Part A or Part B (non-drug) items or services and that its current proposal will limit the ability of MA organizations to use step therapy in connection with non-drug covered items or services that are basic benefits. We support this clarification.

CMS states, “When deciding whether an item or service is reasonable and necessary for an individual patient, we expect MA organizations to make medically necessary decisions in a manner that most favorably provides access to services for beneficiaries and aligns with CMS’s definition of reasonable and necessary in the Medicare Program Integrity Manual, Chapter 13, section 13.5.4.”¹⁶ We applaud CMS for making this statement. The presumption should be that beneficiaries have access to the care and services their providers recommend for their unique needs and circumstances. MA plans should defer to clinical and provider decisions, unless there is a specific and clinically based reason to override such decisions. In such instances, there should be a clear and streamlined avenue for recourse.

CMS proposes that when coverage criteria are not fully established in applicable Medicare statute, regulation, NCD, or LCD, an MA plan may create internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature that is made publicly available. We appreciate the need for flexibility in such circumstances but urge CMS monitoring to ensure this ability is not being used in an inappropriately restrictive way or otherwise abused, and to ensure that updates are made in a timely way when new or updated Medicare determinations are published.

The proposal would require plans to provide a publicly accessible summary of evidence that was considered during the development of the internal coverage criteria used to make medical necessity determinations, a list of the sources of such evidence, and include an explanation of the rationale that supports the adoption of the coverage criteria used to make a medical necessity determination. CMS states that providing a publicly accessible summary of the evidence, a list of the sources of evidence, and an explanation of the rationale for the internal coverage criteria will protect beneficiaries by

¹⁶ 87 FR 79452, 79501.

ensuring that coverage criteria are rational and supportable by current, widely used treatment guidelines and clinical literature. It is unclear if CMS means to require the plan's coverage criteria itself to be publicly available. We urge CMS to require all coverage materials to be publicly available, including the evidence used and the internal coverage criteria.

Transparency is good; however, we caution against assuming beneficiary review of internal coverage criteria will occur or be an adequate safeguard. Not only will the subject matter likely be beyond the comprehension of people outside of the medical field—including most beneficiaries, advocates, and perhaps even clinical non-specialists—but potential enrollees cannot be expected to review the internal coverage criteria for every plan to determine the best fit, especially given the current overabundance of plans and the already pressing difficulty of plan selection. Determining if internal coverage criteria are appropriate is a job for overseeing agencies and committees, not individual enrollees. To the extent that CMS will still allow plans to craft their own utilization management criteria, including on prior authorization, we recommend that CMS consider requiring a public comment period for any MA plan coverage criteria to allow for full consideration of the evidence and rationale by enrollees, providers, and other stakeholders. At a minimum, CMS should explicitly require plans to submit all utilization management tools and criteria to CMS for review as part of a plan's annual bid. Coverage criteria that fail to meet appropriate standards should be cause for contract termination.

We support requiring the internal clinical criteria be based on current evidence in widely used treatment guidelines or clinical literature. We also recommend that CMS continue to review its own statutes, regulations, NCDs, and LCDs to ensure they are current and consistent with clinical criteria developed by nonprofit professional associations for the relevant clinical practice. For example, the American Society for Addiction Medicine (ASAM) Criteria for substance use disorder treatment and the Level of Care Utilization System for Psychiatric and Addiction Services (LOCUS) for mental health treatment.

In addition, CMS proposes to codify existing policy that MA organizations consider the enrollee's entire medical history (for example, diagnoses, conditions, functional status), physician recommendations, and clinical notes when evaluating coverage. We support this codification and urge CMS to add information about family supports. We also encourage strict enforcement against one-size-fits-all algorithms and other tools that fail this requirement.

CMS proposes that MA organizations' medical directors be involved in ensuring the clinical accuracy of medical necessity decisions where appropriate. We support this requirement. Plans, however, should not be the sole arbiters of appropriateness—beneficiaries and their treating clinicians should be able to request such involvement in their appeals.

CMS's proposals would constrain MA organizations' ability to limit when and how covered benefits are furnished when Original Medicare covers different provider types or settings. As a result, when care can be delivered in more than one way or in more than one type of setting, and a contracted provider has ordered or requested Medicare covered items or services for an MA enrollee, the MA organization may only deny coverage if the services or setting fails to meet the coverage criteria as defined in Original Medicare. CMS uses the example of an MA patient being discharged from an acute care hospital and the

attending physician orders post-acute care at a SNF because the patient requires skilled nursing care on a daily basis in an institutional setting. Under the proposed rules and clarifications, the MA organization cannot deny coverage for the SNF care and redirect the patient to home health care services unless the patient does not meet the coverage criteria for SNF care. These are important rules and clarifications. Calls to our national helpline and public reports have revealed that MA organizations are indeed overriding health team recommendations for services and settings, including discharging patients from post-acute care settings too early.¹⁷

3. Appropriate Use of Prior Authorization

CMS proposes to codify that prior authorization should only be used to confirm the presence of diagnoses or other medical criteria and to ensure that the furnishing of a service or benefit is medically necessary or, for supplemental benefits, clinically appropriate, and that it should not function to delay or discourage care. We support this codification. Specifically, we applaud the language clarifying that prior authorization must not be used to derail access to care. As the OIG pointed out in their report on inappropriate denials, “A central concern about the capitated payment model used in Medicare Advantage is the potential incentive for Medicare Advantage Organizations (MAOs) to deny beneficiary access to services and deny payments to providers in an attempt to increase profits.”¹⁸ We have long feared that some plans have coupled upcoding to increase risk adjustment payments with delaying and discourage care in order to reduce expenditures. This combination would lead to greatly increased plan profits, a pattern that appears to be proving true.¹⁹

CMS proposes to codify current guidance that states if the plan approved the furnishing of a service through an advance determination of coverage, it may not deny coverage later on the basis of a lack of medical necessity. We support this codification which will allow enrollees and providers to rely on plan approvals and proceed with care. We urge CMS to ensure MA plans do not deny advance coverage requests in an effort to avoid future obligations.

Finally, CMS reminds plans prior authorization policies are part of plan benefit design and that plan benefit designs may not discriminate against beneficiaries, promote discrimination, discourage enrollment, encourage disenrollment, steer subsets of Medicare beneficiaries to particular MA plans, or inhibit access to services. We applaud this reminder. In our experience, prior authorization plays a role in MA enrollees switching to Original Medicare as they become sicker, including in the last year of life.²⁰ Specifically, that burdensome prior authorization requirements may push sicker, and more costly,

¹⁷ Susan Jaffe, “Nursing Home Surprise: Advantage Plans May Shorten Stays to Less Time Than Medicare Covers” (October 4, 2022), <https://khn.org/news/article/nursing-home-surprise-medicare-advantage-plans-shorten-stays/>.

¹⁸ U.S. Department of Health and Human Services Office of Inspector General, “Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care,” (April 2022), <https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf>.

¹⁹ Kelsey Waddill, “Medicare Advantage Gross Margins Rise 41% Over 2019 Margins,” (October 15, 2020), <https://healthpayerintelligence.com/news/medicare-advantage-gross-margins-rise-41-over-2019-margins>.

²⁰ Government Accountability Office, “MEDICARE ADVANTAGE: Beneficiary Disenrollments to Fee-for-Service in Last Year of Life Increase Medicare Spending,” (June 2021), <https://www.gao.gov/assets/gao-21-482.pdf>.

enrollees out of MA and into Original Medicare, where care is more accessible and coverage more predictable.

In such disenrollment scenarios, the abandoned MA plan reaps financial rewards by avoiding the higher spending associated with the disenrolled beneficiary after collecting premiums and capitated payments during previous, lower cost periods. This cost shifting only incentivizes the plan to continue behaviors that led to the disenrollment, harming an ever-growing number of enrollees.

If people are leaving MA, or certain plans, at high or increasing numbers when they are sicker, something in MA's benefit design, processes, or fundamental structure is making that the rational choice. CMS must investigate, report on, and put an end to these patterns and their causes.

4. Continuity of Care

b. Proposed Regulatory Changes

CMS proposes that MA plans must make all approved prior authorizations valid for the duration of the entire approved prescribed or ordered course of treatment or service. We support this important proposal to ensure enrollees can rely on a full course of treatment. We must flag, however, the risk for MA plans to stint on care on the front end to avoid being locked into authorizing a full course of treatment on the back end. We urge CMS to address this risk.

CMS also proposes that MA organizations must have policies for using prior authorization that provide for a minimum 90-day transition period for any ongoing course(s) of treatment when an enrollee has enrolled in an MA coordinated care plan after starting a course of treatment, even if the course of treatment was for a service that commenced with an out-of-network provider. We support this proposal to avoid disrupting a planned course of treatment or scheduled procedure.

5. Mandate Annual Review of Utilization Management (UM) Policies by a UM Committee (§ 422.137)

a. Review and Approval of UM Policies

CMS proposes that an MA organization that uses utilization management (UM) policies, such as prior authorization, must establish a UM committee that is led by an MA plan's medical director. CMS also proposes that an MA plan may not use any UM policies for basic or supplemental benefits on or after January 1, 2024, unless those policies and procedures have been reviewed and approved by the UM committee, and that UM guidelines must be based on current widely used treatment guidelines or clinical literature. We support these proposals. We encourage CMS to monitor and revisit the activities of such committees to ensure that they are not responding to business incentives to deny and delay care—and to consider requiring: (1) public reporting on committee activities and decisions, (2) beneficiary, advocate, and independent clinician voting involvement in such committees, and (3) CMS participation in and monitoring of such committees.

CMS solicits comment on whether the UM committee must ensure that the UM policies and procedures are developed in consultation with contracted providers; whether the UM committee should ensure

that MA organization communicates information about practice guidelines and UM policies to providers and, when appropriate, to enrollees; and whether the UM committee should have an ongoing or active oversight role in ensuring that decisions made by an MA plan throughout the year are consistent with the final, approved practice guidelines and UM policies. We urge CMS to adopt all these options. Without provider consultation, active communication, and ongoing oversight, UM policies may quickly go out of alignment with the committee's recommendations (which we urge CMS to ensure center beneficiary needs) or the committee may be captured by inappropriate interests.

CMS also proposes that the committee revise UM policies and procedures as necessary, and at least annually, to comply with the standards in the regulation, including removing requirements for UM for services and items that no longer warrant UM so that UM policies and procedures remain in compliance with current clinical guidelines. We support this provision and encourage CMS to require that plans effectively communicate such updates with all relevant providers and impacted enrollees, particularly enrollees who sought and were denied authorization under previous regimes.

CMS solicits comment on whether to require the UM committee to review all internal coverage criteria used by the MA plan. We support this idea. The UM committee is well positioned to review all coverage criteria. Centralizing this review—and making it publicly available—will increase oversight and transparency within the plan, and by outside entities such as CMS.

b. Utilization Management Committee Membership

CMS proposes that the UM committee must include: a majority of members who are practicing physicians; at least one practicing physician who is independent and free of conflict relative to the MA organization and MA plan; at least one practicing physician who is an expert regarding care of elderly or disabled individuals; as well as members representing various clinical specialties (for example, primary care, behavioral health) to ensure that a wide range conditions are adequately considered in the development of the MA plan's utilization management policies. We support these proposals.

CMS solicits comment on whether it should include a requirement that when the proposed UM committee reviews UM policies applicable to an item or service, that the review must be conducted with the participation of at least one UM committee member who has expertise in the use or medical need for that specific item or service. We support including this requirement and urge that the representation be at least two members with expertise, with at least one of the expert members being free of conflict relative to the MA organization and plan.

In addition, we urge CMS to add more specific, enforceable, robust guardrails to ensure that appropriately qualified and non-plan reviewers are involved in decision-making around coverage, in general and in particular for complex services such as post-acute care.

c. Documentation of Determination Process

CMS proposes that the UM committee must clearly articulate and document processes to determine that the composition requirements have been met (that a majority of members are practicing physicians; at least one practicing physician is independent and free of conflict relative to the MA organization and MA plan; at least one practicing physician is an expert regarding care of elderly or disabled individuals; and the committee includes members representing various clinical specialties). CMS also proposes including among the documentation requirements the determination by an objective party of whether disclosed financial interests are conflicts of interest and the management of any recusals due to such conflicts. We support these proposals.

In addition, CMS proposes that the UM committee must document in writing the reason for its decisions regarding the development of UM policies and make this documentation available to CMS upon request. We urge CMS to require the UM committee to submit its documentation to CMS automatically, and to make such materials available to the public and researchers to ensure ongoing compliance and completeness.

6. Additional Areas for Consideration and Comment

a. Termination of Services in Post-Acute Care

CMS solicits comments on MA organizations preauthorizing treatments in discrete increments and the extent to which proposals in this rule may address or limit these practices. Many of these practices are a result of internal coverage rules, decision making guides and practices, executed by computer programs or humans, that do not consider the individual circumstances and needs of each enrollee. Requiring MA plans to develop evidence-based coverage criteria and codifying existing policy that MA organizations consider the enrollee's entire medical history, physician recommendations, and clinical notes would limit these issues somewhat. CMS should monitor for patterns in coverage and denials and investigate to ensure that such decision supports are not being used improperly broadly.

CMS solicits comment on whether enrollees should have additional time to file appeals or be able to file late appeals to the QIO regarding terminations of services. Enrollees have built-in incentives to gain coverage quickly and seamlessly—their health and well-being. Because of this, we support giving additional time and grace periods to enrollees who are often struggling with serious medical issues and, in particular, may be encountering barriers in more than one area of care. The current proposals may help alleviate some of that burden and somewhat lessen attempts by MA plans to win by attrition, but where they do not, additional time will help enrollees gain access to the coverage they are entitled to.

CMS solicits comment on whether enrollees should receive information from the MA plan regarding the basis for termination of services (for example, the clinical rationale for termination of services) as part of the termination notice and without the enrollee having to request an appeal to the QIO. We strongly urge CMS to require this information. Currently, enrollees must go through extra steps to receive basic information that is already available to the plan, such as an adequate explanation of why coverage is being denied or terminated. As a default for all coverage denials and terminations, plans must be required to provide timely, detailed information about their coverage decisions in a manner that makes

it clear what data elements are required, and what might be missing. We also support clearly communicating with the beneficiary about their options and responsibilities.

CMS also solicits comment on when coverage is reinstated based on a QIO decision, whether the enrollee should have more than the 2-day period from the date of a new termination of services notice before coverage can be terminated again by the MA organization, taking into account any medical necessity determinations made by the QIO. We urge CMS to establish a longer time period than 2 days to ensure enrollees are not trapped in an endless cycle of appeals. We recommend a 14-day grace period which would allow a reasonable amount of time to reassess a beneficiary's condition. In addition, an MA organization that repeatedly is overturned by a QIO decision should face investigation and sanctions for inappropriate denials of care.

b. Gold Carding

CMS encourages MA plans to adopt gold-carding programs that would allow providers to be exempt from prior authorization and provide more streamlined medical necessity review processes for providers who have demonstrated compliance with plan requirements. We applaud this encouragement, and support efforts to ease access to covered care and reduce provider burden. CMS should monitor quality, outcomes, and beneficiary satisfaction to ensure that such programs do not reward overly restrictive providers, that providers are not penalized or removed from the program for supporting their patients in appeals or challenges to plan decisions, and that beneficiaries are aware of the option to seek second opinions.

c. Address Vulnerabilities that can lead to Manual Review Errors and System Errors

CMS seeks comment on ways to address and limit MA prior authorization procedures, protocols, and systems. We support this effort and applaud CMS for its information collection. From the beneficiary perspective, care that is denied or delayed due to error can cause immense suffering and hardship, and for no good reason. Generally, reducing the use of prior authorization will also reduce the frequency of overbroad and erroneous denials, as well as avoidable expenses and care delays.

F. Request for Comment on the Rewards and Incentives Program Regulations for Part C Enrollees (§ 422.134 and Subpart V) (p 166)

CMS seeks comment on revising the MA Rewards and Incentives Program regulation to include parameters for permissible gift cards being offered as MA reward items. We oppose the use of gift cards, as we have grave concerns that reward items may entice people to join specific MA plans when other coverage, such as Original Medicare or another MA plan, is a better fit. In addition, the use of gift cards can function to cherry pick enrollees if they are used in targeted ways, intentionally or not.

G. Section 1876 Cost Contract Plans and Cost-Sharing for the COVID-19 Vaccine and its Administration

CMS proposes to require section 1876 cost plans to cover the COVID-19 vaccine and its administration without cost-sharing. We support this requirement.

K. Call Center Interpreter Standards (§§ 422.111(h)(1)(iii)(A) and 423.128(d)(1)(iii)(A))

CMS proposes to require MA organizations and Part D sponsors to use interpreters that adhere to generally accepted interpreter ethics principles, including confidentiality; demonstrate proficiency in speaking and understanding at least spoken English and the spoken language in need of interpretation; and interpret effectively, accurately, and impartially, both receptively and expressively, to and from such language(s) and English, using any necessary specialized vocabulary, terminology, and phraseology. We support this proposal.

M. Part C and Part D Midyear Benefit Changes and Part D Incorrect Collections of Premiums and Cost Sharing (§§ 422.254, 423.265, 423.293, 423.294)

2. Medicare Advantage Prohibition on Midyear Benefit Changes (§ 422.254)

CMS proposes to clarify that any changes to non-prescription drug benefits, cost sharing, and premiums are prohibited starting after plans are permitted to begin marketing prospective contract year offerings on October 1 of each year for the following contract year (consistent with § 422.2263(a)) and through the end of the applicable contract year. We support this clarification.

3. Part D Prohibition on Midyear Benefit Changes (§ 423.265)

CMS proposes to codify a requirement that once a Part D sponsor is permitted to market prospective plan year offerings for the following contract year it must provide the benefits described in its CMS-approved plan benefit package for the contract year without modification, except where a modification in benefits is required by law. We support this codification.

O. Updating Translation Standards for Required Materials and Content (§§ 422.2267 and 423.2267)

1. Standing Request for Translated Materials and Materials in Accessible Formats Using Auxiliary Aids and Services

CMS proposes to require MA organizations and Part D sponsors to provide materials to enrollees on a standing basis in any non-English languages that is the primary language of at least 5% of the individuals in a plan benefit package service area, and in any accessible formats using auxiliary aids and services upon receiving a request for the materials in another language or using auxiliary aids and services or otherwise learning of the enrollee's preferred language or need for an accessible format using auxiliary aids and services. We support this proposal.

2. Require FIDE SNPs, HIDE SNPs, and Applicable Integrated Plans to Translate Materials into the Medicare Translation Standard Plus Additional Medicaid Languages

CMS proposes to require that FIDE SNPs, HIDE SNPs, and applicable integrated plans translate Medicare materials into any languages required by the Medicaid translation standard as specified through their capitated Medicaid managed care contract in addition to the language(s) required by the Medicare

translation standard. We strongly support this requirement and urge CMS to apply this translation requirement to all D-SNPs, including those that do not have matching Medicaid managed care plans.

P. Medicare Advantage (MA) and Part D Marketing (Subpart V of Parts 422 and 423) (p 217)

CMS proposes to require third-party marketing organizations (TPMOs) to gain prior approval from applicable MA organizations or Part D sponsors and submit their marketing materials developed for multiple MA organizations and Part D sponsors (and their specific plans) to CMS through HPMS. We support these requirements, which will better ensure that TPMOs abide by marketing rules and put MA organizations and Part D sponsors on notice about TPMO materials.

CMS proposes to specifically prohibit the use of the Medicare name, CMS logo, or official products, including the Medicare card, in a misleading manner. We support this restriction and encourage a thorough review process to ensure all materials avoid misrepresentation and confusion.

CMS proposes to prohibit the use of superlatives like “best” or “most” unless sources of documentation and/or data supportive of the superlative is also referenced in the material, and to require that such supporting information reflects data points, reports, studies, or other documentation that has been published in either the current or prior contract year. We support this proposal.

CMS also proposes to prohibit MA organizations and Part D sponsors from engaging in marketing that advertises benefits that are not available to beneficiaries in the service area where the marketing appears unless unavoidable in a local market. We support this proposal. Currently, national television ads in particular may create confusion around the availability of benefits, despite some disclaimers. We also encourage CMS to narrowly define “unavoidable” instances.

CMS additionally proposes to prohibit marketing unless the names of the MA organizations or Part D sponsors that offer the benefits being advertised are clearly identified, to help the beneficiary understand they are calling a plan or a plan representative and not Medicare, the government, or a non-partisan entity. CMS proposes that print advertisements must have MA organization, Part D sponsor, or marketing names in 12-point font and may not be solely in the disclaimer or fine print. And that for television, online, or social media-based advertisements, these names must either be displayed during the entire advertisement in the same font size as displayed benefits and phone numbers, or be read at the same pace as advertised benefits or phone numbers. For radio or other advertisements that are voice-based only, CMS proposes the names be read at the same speed as the phone number. We support these proposals, which we hope will make the materials clearer and less misleading to consumers. We recognize additional refinements may be needed to achieve CMS’s stated goals, and urge the agency to solicit beneficiary feedback and engage in consumer testing to ensure the proposed and any future guardrails are maximally effective.

CMS also proposes to prohibit MA organizations and Part D sponsors from including information about savings available to potential enrollees that are based on a comparison of typical expenses borne by uninsured individuals, unpaid costs of dually eligible beneficiaries, or other unrealized costs of a

Medicare beneficiary. We support this proposal. Further, we suggest that CMS prohibit plans from marketing benefits that are mandated for all plans—such as the availability of the Medicare Savings Program, insulin copays of \$35 a month, free vaccines, or the statutory out-of-pocket cap—without clarifying that these are general program benefits.

CMS proposes to clarify that contacting a beneficiary at his or her home is considered door-to-door solicitation unless an appointment at the beneficiary’s home at the applicable date and time was previously scheduled. We support this proposal.

CMS is proposing to require each MA organization and Part D sponsor to provide the opt-out information to all its enrollees, regardless of plan intention to contact, at least annually in writing, instead of just one time. We strongly support this proposal.

CMS also proposes to amend the list of permissible marketing activities to no longer include educational events by removing the paragraphs that authorize obtaining beneficiary contact information, including Scope of Appointment forms. In addition, CMS proposes removing permission for organizations and agents to set up future marketing appointments at educational events, and to prohibit marketing events from taking place within 12 hours of the educational event in the same location. We support these proposals. Beneficiaries must not feel pressured to fill out forms, agree to appointments, or to give other permissions in conjunction with educational events. Educational events should be distinct in time and place, and a risk-free opportunity for people to learn more about how MA and Part D plans work.²¹

CMS proposes to require at least 48 hours between agreeing and recording the Scope of Appointment and the start of the personal marketing appointment. We support this requirement. Despite current rules, which allow the 48-hour waiting period to be eliminated if it is not “practicable,” we have heard from beneficiaries who found themselves immediately in an appointment, likely because the marketing organization chose to view the “when practicable” language as extremely permissive.

CMS is proposing to limit the validity of both the Scope of Appointment and Business Reply Cards to six months from the beneficiary’s signature date or request for more information, respectively. We support this proposal and recommend further shortening the time frame. Such contact permissions should be extremely limited in duration and scope, never open-ended.

CMS proposes to require the organization’s provider directory be searchable by every element required in the model provider directory (such as name, location, and specialty) to better assist beneficiary searches. CMS also proposes that the providers’ cultural and linguistic capabilities and the identification of those able to treat patients with MOUD, discussed above, be searchable. We support these proposals and reiterate the need for more accurate provider directories in general.

CMS is proposing to add “effect on current coverage” to the list of information that plans must include in the pre-enrollment checklist (PECL), to better communicate the implications of choosing an MA or

²¹ Center for Medicare Advocacy, Justice in Aging, National Council on Aging, & Medicare Rights Center, “Joint Letter,” (August 27, 2019), <https://www.medicarerights.org/pdf/082719-mpf-mcmg-2020-letter-cms.pdf>.

Part D plan. CMS is also proposing that the PECL be reviewed with prospective enrollees during telephonic enrollments as well as provided with hard-copy enrollment forms. We support these efforts to improve beneficiary understanding. We urge CMS to include additional information in the PECL, including about the plan's use of utilization management and enrollee rights to seek care outside of a plan's network if they are unable to access care timely within the network.

CMS also proposes to require all plans to list certain benefits at the beginning of the Summary of Benefits and in a specified order, allowing beneficiaries to compare plans in a more standardized way. We strongly support this proposal.

In addition, CMS proposes to label the non-renewal notice as a "standardized communications material" and not a "model," to clarify plan modifications are strictly limited. This is necessary to ensure that vital information in the non-renewal notice about a beneficiary's alternative health care options and the timing for the plan to make a selection are conveyed in a way that CMS has determined is accurate and understandable. We support this important specification.

CMS proposes to require new disclaimers for TPMO marketing materials to give prospective enrollees other, unbiased, sources of information about their coverage options. The first disclaimer, for TPMOs that do not sell for all MA organizations or Part D sponsors in a service area, would read, "We do not offer every plan available in your area. Any information we provide is limited to those plans we do offer in your area which are [insert list of MA organizations or Part D sponsors]. Please contact Medicare.gov, 1-800-MEDICARE, or your local State Health Insurance Program to get information on all of your options." The second disclaimer, for TPMOs that do sell for all MA organizations or Part D sponsors in a service area, would read, "We offer the following plans in your area [insert list of MA organizations or Part D sponsors]. You can always contact Medicare.gov, 1-800-MEDICARE, or your local State Health Insurance Program for help with plan choices." We support this proposal.

CMS proposes to require that sponsoring organizations have an agent and broker monitoring and oversight plan in place that ensures agents and brokers are adhering to CMS requirements and allows for active monitoring and reporting of agents and brokers to CMS for non-compliance. We support this proposal and urge CMS to mandate sanctions for plans to impose when inappropriate behavior is identified, such as withholding commissions from the offending agent or broker.

CMS is proposing to require an MA organization or Part D sponsor to ensure that the agent's/broker's sales call goes over each CMS required question or topic, including information regarding primary care providers and specialists (that is, whether or not the beneficiary's current providers are in the plan's network), prescription drug coverage and costs (including whether or not the beneficiary's current prescriptions are covered), costs of health care services, premiums, benefits, and specific health care needs. CMS would provide in sub-regulatory guidance more detailed questions and areas to be covered based on these general topics. In addition, CMS proposes to require the recording of all marketing, sales, and enrollment calls including calls occurring via web-based technology, in their entirety. We support these proposals.

CMS proposes to state that “Personal beneficiary data collected by a TPMO may not be distributed to other TPMOs.” We support this addition to provide greater privacy for beneficiaries.

R. Part D Medication Therapy Management (MTM) Program (§ 423.153(d))

1. MTM Eligibility Criteria (§ 423.153(d)(2))

b. Multiple Chronic Diseases

CMS proposes to amend the regulations to require all Part D sponsors to include all core chronic diseases when identifying enrollees who have multiple chronic diseases. We support this proposal.

CMS also proposes to codify the 9 core chronic diseases currently identified in guidance and to add HIV/AIDS, for a total of 10 core chronic diseases. We support this proposal as well. Individuals with HIV/AIDS often have very high Part D drug costs and multiple comorbidities, and are more likely to be members of populations affected by disparities. In addition, they are likely to have complex Part D drug regimens where medication adherence is critical. Despite these needs, people aging with HIV continue to face obstacles to accessing vital care. Adding HIV/AIDS as a core chronic disease will improve access to additional supports and services.

c. Multiple Part D Drugs

CMS proposes to decrease the maximum number of Part D drugs a sponsor may require from 8 to 5 for plan years beginning on or after January 1, 2024. We support this proposal.

CMS also proposes to require plans to rely on information contained within a widely accepted, commercially or publicly available drug information database commonly used for this purpose of identifying maintenance drugs. In addition, sponsors would be required to target all Part D maintenance drugs. We support these changes.

d. Annual Cost Threshold

CMS proposes to set the MTM cost threshold for the 2024 plan year and each subsequent plan year at the average annual cost of 5 generic drugs. We support this proposal.

IV. Strengthening Current Medicare Advantage and Medicare Prescription Drug Benefit Program Policies

B. Defining Institutional Special Needs Plans and Codifying Beneficiary Protections (§ 422.2)

We have grave concerns with I-SNPs and urge CMS to consider whether these plans are appropriately serving the needs of people with Medicare. In our experience, most I-SNP enrollees would be better served in a D-SNP or in Original Medicare, as such coverage avoids the strong incentives of institutional actors. One particular concern is whether I-SNPs are taking adequate steps to assist their members who wish to return to the community. Those I-SNPs that are owned by skilled nursing facility providers have little incentive to create empty beds in their own facilities.

V. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (42 CFR 422.162, 422.164, 422.166, 422.260, 423.182, 423.184, and 423.186) (p 513)

G. Health Equity Index Reward (§§ 422.166(f)(3) and 423.186(f)(3))

Medicare Rights is generally supportive of the efforts to increase equity within Medicare and Medicare Advantage outlined in this proposed rule. As such, we applaud the extensive and sensitive exploration of the value of a Health Equity Index Reward and support its creation. However, we have significant concerns that the current star ratings program's relationship to MA quality is tenuous and becoming more distant as MA organizations find ways to game the system and reap additional rewards, including by exploiting processes and loopholes. The star ratings program needs important reforms to ensure it is truly strengthening transparency, holding MA programs accountable, and resulting in improved care and increased savings for enrollees. We have been encouraged by CMS's recent decisions to press for more information from MA organizations, which will begin to fill some data holes and to eliminate some of the program's opacity. But we have little confidence in the relationship between current measures/star ratings and the actual health, well-being, and access to appropriate care of MA enrollees.

We urge CMS to ensure that the any Health Equity Index Reward, and the entire star ratings system, reflects actual value for Medicare, enrollees, and taxpayers.

Conclusion

Thank you again for the opportunity to provide comment. For additional information, please contact Lindsey Copeland, Federal Policy Director at LCopeland@medicarerights.org or 202-637-0961 and Julie Carter, Counsel for Federal Policy at JCarter@medicarerights.org or 202-637-0962.

Sincerely,



Fred Riccardi
President
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